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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/423,516	02/10/2000	ERMANNO GHERARDI	1090-26	6832

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NIXON & VANDERHYE, PC
1100 N GLEBE ROAD
8TH FLOOR
ARLINGTON, VA 22201-4714

EXAMINER

HAYES, ROBERT CLINTON

ART UNIT	PAPER NUMBER
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1647

DATE MAILED: 01/09/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application N .

09/423,516

Applicant(s)

GHERARDI ET AL.

Examiner

Robert C. Hayes, Ph.D.

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on 21 March 2003.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 64-86 is/are pending in the application.
- 4a) Of the above claim(s) 80-86 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 64-79 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) 64-86 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 21 March 2003 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☒ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. §§ 119 and 120

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 13) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.
a) ☐ The translation of the foreign language provisional application has been received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____
- 4) ☐ Interview Summary (PTO-413) Paper No(s) _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other:

DETAILED ACTION

Response to Amendment

1. The amendments filed 11/27/02 and 3/21/03 have been entered.
2. The rejection of claims 31-41 & 49-54 under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter is withdrawn due to the cancellation of the claims, and Applicants' arguments.
3. The rejection of claim 31-41 & 49-54 are rejected under 35 U.S.C. 112, second paragraph, for the recitation, "which is *substantially* incapable of binding....", is withdrawn due to the cancellation of these claims.
4. The rejection of claims 33-35 & 51-54 under 35 U.S.C. § 112, second paragraph, for lack of proper antecedent basis is withdrawn due to the cancellation of these claims.
5. The rejections of claims 31-32 & 34 under 35 U.S.C. 102(a) as being anticipated by Sakata et al and Lokker et al are withdrawn due to the cancellation of these claims and Applicants' arguments that these references do not teach substitution "with a negatively charged residue".

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6. Newly submitted claims 80-86 are directed to an invention that is independent or distinct from the invention originally claimed for the following reasons:

Originally elected Group I was directed to variant HGF polypeptide products, which is not a special technical feature. In contrast, the new claims submitted are directed to methods, in which the technical features of this new Group invention is not present in the Group I claims. Again, note that PCT Rule 13 does not provide for multiple products or methods within a single application.

Since applicant has received an action on the merits for the originally presented invention, this invention has been constructively elected by original presentation for prosecution on the merits. Accordingly, claims 80-86 are withdrawn from consideration as being directed to a non-elected invention. See 37 CFR 1.142(b) and MPEP § 821.03.

This application contains claims 80-86 drawn to an invention nonelected with traverse in Paper No. 17. A complete reply to the final rejection must include cancellation of nonelected claims or other appropriate action (37 CFR 1.144) See MPEP § 821.01.

7. The oath or declaration remains defective, for the reason made of record in Paper No: 18 (mailed 6/27/02). A new oath or declaration in compliance with 37 CFR 1.67(a) identifying this application by application number and filing date is required. See MPEP §§ 602.01 and 602.02.

8. Applicant's arguments filed 11/27/02 have been fully considered but they are not deemed to be persuasive.

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9. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

10. Claims 64-79 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention, for the reason made of record for cancelled claims 31-32 & 49-50 in Paper No: 18 (mailed 6/27/02), and as follows.

In contrast to Applicants' assertions on page 9 of the response, base claim 64 recites no structure and, as claimed, is not limited to a variant that merely replaces "a positively charged amino acid residue in the hairpin loop structure [which is not structurally defined] of wildtype human HGF [which is not structurally defined]... with an amino acid residue with a negative charge"; thereby, still not meeting the written description guidelines as discussed in Example 13 in the Revised Interim Utility and Written Description Guidelines, Federal Register, Vol.64, No.244, pages 71427-71440, Tuesday December 21, 1999, as well as in MPEP 2163, for the reasons previously made of record. In other words, it remains unknown and not described what structurally constitutes such generic "variant HGF" polypeptides.

Analogous to the situation decided in *Fiers v. Revel*, 25 USPQ2d 1601, 1606 (Fed. Cir. 1993), "an adequate written description of a DNA [product] requires more than a mere statement that it is part of the invention and reference to a potential method for isolating it; what is required is a description of the DNA itself". *Fiddes v. Baird*, 30 USPQ2d 1481, 1483 (1993) held that claims directed to mammalian FGF's were found unpatentable due to lack of written

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description for the broad class, in which the specification had provided an adequate description of only the bovine sequence. Similarly, only a single human polypeptides species (i.e., human HGF of SEQ ID NO:2) has been described in the instant specification.

Accordingly, the court held in *Univ. California v. Eli Lilly and Co.*, 43 USPQ2d 1398 (Fed. Cir. 1997) that:

"One skilled in the art therefore cannot, as one can do with a fully described genus, visualize or recognize the identity of the members of the genus. A definition by function, as we have previously indicated, does not suffice to define the genus because it is only an indication of what the gene does, rather than what it is",

and that:

"A description of a genus of cDNAs [products] may be achieved by means of a recitation of a representative number of cDNAs [products], *defined by nucleotide sequence*, failing in the scope of the genus or of a recitation of structural features common to the members of the genus, *which features constitute a substantial portion of the genus* [emphasis added]. This is analogous to enablement of a genus under 112, [first paragraph], by showing the enablement of a representative number of species within the genus. See Angstadt, 537 F.2d at 502-03, 190 USPQ at 218".

Thus, Applicants are not reasonably in possession of the claimed genus of variant HGF polypeptides at the time of filing the instant application, as currently claimed.

11. Claims 64-79 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for claims limited to HGF variants that are structurally characterized and claimed, does not reasonably provide enablement for any biologically functional equivalent forms of HGF with no recited structural characteristics. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention commensurate in scope with these claims, for the reason made of record for cancelled claims 31-32 & 49-50 in Paper No: 18 (mailed 6/27/02), and as follows.

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In contrast to Applicants' assertions on pages 9-10 of the response, no base structure for what constitutes the wildtype HGF from which the variant HGF molecule is derived is defined in the currently recited claims, which includes which or what "hairpin loop structure" is to be mutated in these uncharacterized molecules. Therefore, Applicants' arguments are moot, for the reasons previously made of record; consistent with the teachings of Rudinger previously made of record.

Accordingly, it was held in *Ex parte Maizel* (27 USPQ2d 1662 at 1665) that:

Appellants have not chosen to claim the DNA [product] by what it is but, rather by what it does, i.e., encoding either a protein exhibiting certain characteristics, *or* a biologically functional equivalent thereof. Appellants' claims might be analogized to a single means claim of the type disparaged by the court of customs and Patent Appeals in *In re Hyatt*, 708 F.2d 712, 218 USPQ 195 (Fed. Cir. 1983). The problem with the phrase "biologically functional equivalent thereof" is that it covers any conceivable means, i.e., cell of DNA or plasmid, which achieves the stated biological result while the specification discloses, at most, only a specific DNA segment known to the inventor. Clearly, the disclosure is not commensurate in scope with the claims."

Lastly, claims 74-77 recite negative claim language (i.e., "provided that the variant HGF is not a variant of human HGF in which replacements (a)... or (b)... have been made), which does not define the invention, but rather attempts to claim an invention by excluding what is not invented. However, the courts have held that negative limitations that exclude compounds do not meet the requirements of 35 U.S.C. 112 because it attempts to claim the invention by excluding what was not invented rather than what was invented. *In re Schechter*, 205 F.2d 185, 98 USPQ 144 (CCPA 1953).

12. Claims 64-79 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as

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the invention, the reason made of record for cancelled claims 33-35 & 51-54 in Paper No: 18, and as follows.

It remains confusing how changes at position numbers related to SEQ ID NO: 2 are to be made if the wildtype human HGF molecule is itself not defined as SEQ ID NO: 2; especially when the base uncharacterized wildtype HGF molecule may possess a different number of amino acid residues, such as no N-terminal Met residue, etc., as previously made of record.

13. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a).

Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

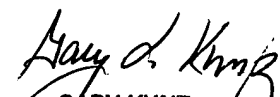
Any inquiry concerning this communication or earlier communications from the examiner should be directed to examiner Robert Hayes whose telephone number is (703) 305-3132. The examiner can normally be reached on Monday through Thursday, and alternate Fridays, from 8:30 AM to 5:30 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Kunz, can be reached on (703) 308-4623. The fax phone number for this Group is (703) 872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196.



Robert C. Hayes, Ph.D.
January 6, 2003



GARY KUNZ
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600